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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,605

08/18/2005

Takehiro Miwa

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EXAMINER

ARIANI, KADE

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,605	Applicant(s) MIWA ET AL.	
	Examiner Kade Ariani	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/04/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on December 04, 2007, has been received and entered.

Claims 1-20 are pending in this application and were examined on their merits.

Election/Restrictions

Applicant's election with traverse of Group I claims 1-3, 5, 6, 8, 13-18, and 20 in the reply is acknowledged. The traversal is based on the relationship of claim 4 (Group III) to claims 1 (Group I), in that regard Applicant has amended claim 4 to clarify the relationship and make it dependent on claim 1.

The traversal is based on the ground that the not only the method of claims 6, 17, 18, and 22, but also the method of claims 9-11 are *in vitro*.

Upon reconsideration, the requirement for restriction is withdrawn.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 7 provides for the use of an enzyme, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant

is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 7 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102 (b), as being anticipated by Olsen et al. (WO98/30682-A1).

Claims 1- 5 are directed to an agent comprising as an active ingredient an enzyme, and the enzyme is an enzyme comprising the amino acid sequences of SEQ ID NO: 2.

Olsen et al. disclose an enzyme comprising the amino acid sequences of SEQ ID NO: 2, and a modified enzyme composition.

Olsen et al. do not disclose the properties of the enzyme. However, the claimed enzyme (active ingredient) appears to be the same to that of the prior art, therefore, it must have the same physical, chemical, and catalytic properties.

Olsen et al. therefore clearly anticipate the claimed agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shih et al. (US2002/0172989 A1) and Olsen et al. (WO 98/30682-A1).

Claims 1-20 are drawn to an agent comprising as an active ingredient an enzyme, the enzyme is an enzyme comprising the amino acid sequences of SEQ-ID NO: 2, a method for digesting a protein highly resistant to denaturation and degradation (a pathogenic prion protein) comprising the step of bringing the protein into contact with the agent, without preheating the subject at 90°C.

Shih teach a method for digesting of infectious prion proteins comprising the step of bringing the protein into contact with an agent, the enzyme is derived from *Bacillus licheniformis* (Abstract, Page 1 0002, 0006,0010, and Page 3 0054), and without preheating the subject at 90°C (page 2 0031).

Shih teach the proteolytic enzyme be of any suitable type it will be recognized that any of a wide variety of proteases may be employed in the practice of the invention, and that the choice of specific proteolytic enzyme will affect the choice of temperature that is used to carry the proteolytic degradation, as well as the choice of any elevated temperature treatment of the tissue before its exposure to the proteolytic enzyme (Page 3, 0046).

Shih further teach proteolytic enzymes include keratinase enzymes, subtilisin, and active fragments of a keratinase enzyme (Page 3 0053-0054).

Shih does not teach an enzyme comprising the amino acid sequences of SEQ ID NO: 2. However, Olsen et al. teach subtilisin, an enzyme comprising the amino acid sequences of SEQ ID NO: 2.

Moreover, Shih teach the method achieves a substantial advance in the art, permitting nutritional use of a material that would otherwise, in the absence of the treatment, constitute a biological hazard, and to avoid costs and infrastructure requirements for incineration and disposal of infected or contaminated animal tissue (page 4 0071).

Therefore, it would have been obvious to one of ordinary skill in the art to combine the above teachings and to use the enzyme (subtilisin) as taught by Olsen et al. in the composition and the method of Shih to provide an agent and the method for digesting a pathogenic prion protein(a protein highly resistant to denaturation and degradation). The motivation for the combination would be to increase the degrading capacity of the enzyme composition, and thus permitting nutritional use of a material that would otherwise, in the absence of the treatment, constitute a biological hazard, and to avoid costs and infrastructure requirements for incineration and disposal of infected or contaminated animal tissue.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/
Primary Examiner, Art Unit 1651

Kade Ariani
Examiner
Art Unit 1651

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